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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,059	07/18/2000	Linda R. DeYoung	GENENT.047C1	2106

7590 06/11/2002  
KNOBBE, MARTENS, OLSON & BEAR, LLP  
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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/11/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/619,059

Applicant(s)

DEYOUNG ET AL.

Examiner

Marianne Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 April 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 2-21 are under consideration by the examiner.

Applicant's arguments filed 4/5/02 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Double Patenting***

The terminal disclaimer filed on 4/5/02 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,090,781 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Claim Rejections - 35 USC § 112***

Claims 2-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "pharmaceutically effective amount of nerve growth factor." However, the claim fails to indicate the condition that this amount is effective for. In the absence of such a condition, the metes and bounds of the amount of NGF encompassed by the claims cannot be determined. Applicant's arguments are unpersuasive. The specification does not provide the amounts that would be effective for each and every disorder that could be treated with NGF. It is unclear whether the specification discloses all disorders that could be treated with NGF. As such, it cannot be determined from the specification what compositions are encompassed by the claims.

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The recitation "at least about 0.1 mg/ml" in claim 13 is ambiguous in that the metes and bounds intended are not clear. Applicant's arguments are unpersuasive. Applicant is requested to state on the record what the plain meaning of this phrase is and the exact amounts of NGF that one of ordinary skill in the art would know that it included.

***Claim Rejections - 35 USC § 102***

Claims 2, 4, 12, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Calbiochem 1994/1995 product catalog.

This rejection is maintained for reasons of record. Applicant argues that the buffer is not of pharmaceutically acceptable quality. Applicant's specification does not provide any discussion of the quality characteristics required and it is applicant's burden to demonstrate that the buffer of the prior art does not meet the undisclosed standard being applied. Note that the specification does not provide any particular level of quality to be pharmaceutically acceptable.

Claims 2, 4-5, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Apfel et al. (Annals of Neurology, 29(1): 87-90, January 1991).

This rejection is maintained for reasons of record. Applicant argues that the buffer is not of pharmaceutically acceptable quality. Applicant's specification does not provide any discussion of the quality characteristics required and it is applicant's burden to demonstrate that the buffer of the prior art does not meet the undisclosed standard being applied. Note that the specification does not provide any particular level of quality to be pharmaceutically acceptable.

Claims 2-6, 11-14, 17-18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Della Valle et al. (U.S. Patent No. 5,210, 185).

This rejection is maintained for reasons of record. Applicant argues that the buffer is not of pharmaceutically acceptable quality. Applicant's specification does not provide any discussion of the quality characteristics required and it is applicant's burden to demonstrate that the buffer of the prior art does not meet the undisclosed standard being applied. Note that the specification does not provide any particular level of quality to be pharmaceutically acceptable.

Claims 2-3, 5-6, 11-14, and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Knepp et al. (WO 95/058845).

This rejection is maintained for reasons of record. Applicant argues that the buffer is not of pharmaceutically acceptable quality. Applicant's specification does not provide any discussion of the quality characteristics required and it is applicant's burden to demonstrate that the buffer of the prior art does not meet the undisclosed standard being applied. Note that the specification does not provide any particular level of quality to be pharmaceutically acceptable.

***Claim Rejections - 35 USC § 103***

Claims 2-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over della Valle et al. in view of Remington.

This rejection is maintained for reasons of record and in view of the above remarks concerning pharmaceutically acceptable quality.

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Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over della Valle et al. (U.S. Patent No. 5,210,185) in view of Heinrich (U.S. Patent No. 5,082,774) and della Valle et al. (U.S. Patent No. 5,457,034).

This rejection is maintained for reasons of record and in view of the above remarks concerning pharmaceutically acceptable quality.

Claims 2-14 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knepp et al. (WO 95/058845) in view of della Valle et al. (U.S. Patent No. 5,210,185), Heinrich (U.S. Patent No. 5,082,774), Remington, Schmelzer et al. (Journal of Neurochemistry, 1992), and O'Connor et al. (U.S. Patent No. 5,763,394).

This rejection is maintained for reasons of record and in view of the above remarks concerning pharmaceutically acceptable quality.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

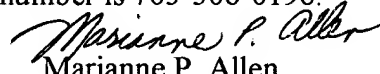
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

mpa  
June 10, 2002